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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,753	WATKINS ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 5-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, and 5-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/04 has been entered.

The amendment and response filed 5/4/04 have been entered. Claim 4 has been canceled. Claim 1 has been amended. Claims 1, and 5-13 are pending in the application and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in the response filed 5/4/04 would be addressed to the extent that they apply to current rejection.

Claim Objections

Claim 1 is objected to because the word "in" in line 19 should be deleted, the word "wherein" should be inserted before "the vaccine" in line 5, and before "the sequence" in line 8.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, and 5-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because of the claim recitation "a viral infection associated with a viral polyepitope", the meaning of the word "associated", and hence the phase as a whole is unclear in the context of the claim, thus the metes and bounds of the claim is uncertain.

Claims are vague and indefinite because the preamble of claim 1 provides a method of inducing an epitope-specific CTL response against a viral infection associated with a viral *polypeptide* in a human subject, wherein the body of the method step recites "induce in the human a cytotoxic T lymphocyte response specific for the MHC class I-restricted peptide *epitope*" (lines 9-11); and "wherein the response invokes CD3+/CD8a+ T lymphocytes...specific for the *epitope*". Here, the resolve of the method steps does not relate back to the preamble.

Claim 5 recites the limitation "the viral epitope". There is insufficient antecedent basis for this limitation in the claim. Particularly, considering claim 5 depends from claim 1, which recites "viral polyepitope", "a MHC class I-restricted peptide epitope" derived from a virus, and "a HIV epitope", it is unclear, which of these epitopes and polyepitopes the term refers to, and thus the metes and bounds of the claim are uncertain.

Claim 9 recites the limitation "the epitope-specific cytotoxic T lymphocyte response of step (b)". There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 5-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inducing an epitope-specific CTL against HIV infection in a human comprising first delivering into cells of the human a *plasmid* polynucleotide vaccine as defined in step (a) of claim 1 by gene gun-mediated *intradermal* (subcutaneous) injection followed by a *viral* vector vaccine as defined in step (b) of claim 1, wherein the vaccine invokes a epitope-specific T lymphocyte response, wherein at least 8.3% of the lymphocytes are CD3/CD8a+, and specific for the MHC class I-restricted peptide epitope, wherein the antigenic viral epitopes used in both step (a) and (b) are derived from HIV virus and are the same for the MHC class I peptide epitope and viral polyepitope, does not reasonably provide enablement for inducing such levels of CTL by any route of administration and using different combinations of HIV and other viral epitopes and polyepitopes in steps a) and (b). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention are summarized in *In re Wands*, (858 F2d 731, 737, 8 USPQ 2d 1400, 1404, (Fed Cir.1988)). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided. The factors most relevant to this rejection are the scope of the claims relative to the state of the art and the levels of the skilled in the art, and whether sufficient amount of direction or guidance are provided in the specification to enable one of skill in the art to practice the claimed invention.

Claim 1 requires inducing a viral epitope specific CTL response at a specific level, and the disclosure of the specification teaches that such level of response was achieved by a particular mode of administration of a plasmid polynucleotide using the PowderJect XR gene delivery system. The specification is silent with regard to using other types of polynucleotide delivery vector and other routes of administration.

In view of the state of the art concerning the routes of genetic vaccination, *McCluskie et al* (Mol Med 1999 May;5:287-300) teach "ROUTES OF ADMINISTRATION OF PLASMID DNA VACCINES INFLUENCES THE STRENGTH AND NATURE OF IMMUNE RESPONSES IN MICE AND NON-HUMAN PRIMATES. *Torres et al* (J Immunol 1997;158:4529-32) teach "TRANSFECTED CELLS IN GENE GUN-BOMBARDED SKIN, BUT NOT NEEDLE-INJECTED MUSCLE, PLAY A CENTRAL ROLE IN DNA-INITIATED AB AND CTL RESPONSE" (abstract). *Nakano et al* (J Virol 1997;71:7101-09) teach that immune reactivity with plasmid DNA encoding HCV-E2 antigenic domains is

linked to the injection mode, "DIFFERENT ROUTES OF INJECTION OF HCV E2 PLASMID CAN RESULT IN QUANTITATIVELY AND QUALITATIVELY DIFFERENT HUMORAL IMMUNE RESPONSES" (see abstract). Apparently, the claimed levels of the CTL response achieved by the gene gun delivery system may not be obtainable by other types of delivery. For example, the response disclosed by *Hanke et al* was elicitated by intravenous and intramuscular routes of administration, and obtained a CTL response much less significant as instantly claimed, yet the method is fully encompassed by the instant claimed method. Accordingly, it appears that the specification fails to provide an enabling disclosure to support the full scope of the claims.

Moreover, the use of gene gun delivery system is routinely associated with the use of a plasmid polynucleotide due to the low efficiency of a plasmid entering cells. The specification is silent concerning whether using any type of polynucleotide delivered by any route, e.g. intramuscular or intravenous injection could achieve the required levels of the CTL response, thus fails to provide an enabling disclosure to support the full scope of the invention.

Given the broadest reasonable interpretation, claim 1 encompasses a process using the HIV vaccine in step (a), and any other viral antigen in step (b). Since it is a common knowledge that different antigens would induce different types of epitope-specific immune responses, it is unknown and the specification fails to teach whether such combination of step (a) and (b) would induce an HIV epitope-specific CTL response at the levels recited in claim 1. Hence, the specification fails to provide an enabling disclosure to support the full scope of the claims.

Therefore, in view of the limited guidance, the lack of predictability of the art and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation as it is broadly claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b). (8.33)

Claim 1 stands provisionally rejected and claims 5-13 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-22, 24-28 of copending Application No. 09/434,830. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 19-22 and 24-28 of the copending Application No. 09/434,830 embrace the instant claims.

Applicants indicated in the 5/4/04 response that the amended claim 1 is specifically drawn to an HIV viral antigen and administering such to a human subject, thus this rejection should be withdrawn.

In response, it is noted that although the viral antigen in step (a) of the claim 1 is now limited to HIV virus, step (b) of the claim 1 remains drawn to any viral antigen.

Moreover, assuming the claims will be amended to limit the viral antigen in both steps to HIV virus, using HIV antigen is taught in the specification of the cited application as preferred embodiment of the antigens, the CTL response is exemplified in the working examples in the mouse and primate models, and the levels of the CTL response is also disclosed in the specification (e.g. page 30, table 1 of the specification of the cited patent application). Further, using the particle bombardment method delivering a polynucleotide into cells of human and primates are also claimed in the cited patent application.

Accordingly, the invention as claimed remains co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claim 1 stands provisionally rejected and claims 5-13 are newly rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/434,830 which has two common inventors with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

The amended claim is specifically drawn to an HIV viral antigen, which is taught in the specification of the cited application (e.g. page 8, 3rd & 4th paragraph). Therefore, the cited application anticipates the instant claim.

Claim 1 stands rejected and claims 5-13 are newly rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. As discussed in the immediate preceding rejection, the process of instant claims is anticipated by the cited patent application, however, the inventive entities are different between two applications. Further clarification is required regarding who is the inventor for the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, and 5-13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Fuller et al* (Immunol Cell Biol 1997;75:389-96) and *Fuller et al* (Vaccine 1997;15:924-5), in view of *Hanke et al* (J Gen Virol 1998 Jan;79:83-90), *Borgne et al* (Virol 1998;240:304-15), and further in view of *Loktev et al* (J Biotechnol 1996;44:129-37).

Amended claim 1 limits HIV virus as the target of a polynucleotide vaccine in step (a) of the vaccination process, which is fully taught in the combined teachings of the cited references.

The first reference of *Fuller et al* teaches a gene gun-based nucleic acid vaccination method for SIV in a primate (rhesus macaques) combined with a live recombinant vaccinia viral vector comprising a polynucleotide sequence expressing SIV env epitope (gp160) as a booster immunization (abstract). Before receiving the booster dose of the vaccinia virus (DNA+VAC), the rhesus macaques received seven consecutive doses of the nucleic acid vaccine expressing an env polypeptide of SIV (gp120 and gp160) driven by a CMV intron A promoter (Expression vectors, page 390), and certain group of macaques received more than one vaccinia virus (VAC+VAC). In

the subsequent challenge with infectious doses of SIV (comprising the epitope of gp120 and gp160), all vaccine groups showed significant reduction in SIV virus load when compared to controls. *Fuller et al* go on to teach that using repeated DNA immunization alone would lead to a significant decline in antibody response to virus, and this may be overcome by combining DNA priming with protein or recombinant vaccinia virus boosts (paragraph bridging pages 393-4).

The second reference of *Fuller et al* elaborates the teachings of the first one, and teaches that in contrast to DNA vaccination for influenza and hepatitis B, DNA plasmid coding for antigens from SIV and *HIV* have elicited relatively weak antibody responses, but boosting gene gun-primed animals with either recombinant subunits or gp120-expressing recombinant vaccinia virus could achieve synergistic responses (abstract) and dramatically improve antibody response (Section in page 926). They teach DNA constructs expressing HIV env, or gag-pol-env (Section in page 925) as well as SIV (Section in page 924 and 926). The two *Fuller et al* references do not teach HBcAg or MHC class I-restricted peptide epitope.

Hanke et al supplemented the teachings of *Fuller et al* by establishing that it is well known in the art CTL response is critical for developing HIV vaccine, and such could be achieved by including CTL epitope in the antigen-expressing vectors. *Hanke et al* teach to include a multi-CTL epitope (MHC class I-restricted peptide epitope) in the vaccine for HIV (abstract). They teach the importance of eliciting a CD8+ (cytotoxic T lymphocyte) response in the development of an HIV vaccine, and they construct a modified vaccinia virus Ankara (MVA) expressing multi-CTL epitope derived from

immunodeficiency virus (a portion of an HIV env polypeptide) consisting of 20 human, one murine and three rhesus macaque epitope and administering the recombinant MVA into mice (H epitope, left column, page 84). They teach to include antigens from mice and macaques in order to conduct pilot study for an optimal vaccine regimen, such as optimal dosage and routes of administration, before a trial applied in humans. They delivered the vaccine by intravenous and intramuscular injection, and obtained specific CTL responses via both routes of administration (pages 86-87). Fig. 4 illustrates IFN-γ-producing cells upon stimulation with HIV epitope. Because the method steps and type of CTL and viral epitopes used in the cited reference are embraced by instant claims, the epitope-specific cytotoxic T lymphocyte response would be detectable by tetramer staining of fresh unstimulated polymorphonuclear blood cells, and fresh unstimulated polymorphonuclear blood cells from these primates would produce IFN-γ. *Hanke et al* further tested the H epitope in cultivated human cells, and observed correct processing and presentation of H epitope in human cells (fig. 5). *Hanke et al* carried the experiments in mice and human cells in vitro, but not *in vivo*.

Borgne et al supplemented the teachings of *Fuller et al* and *Hanke et al* by establishing that including a hepatitis B virus-based vector could be used for inducing a strong CTL response against an HIV antigen epitope, and by establishing that such response could be induced in mice and primates alike (e.g. abstract). *Borgne et al* teach inducing a specific CTL response to HIV in both mice and rhesus macaques with a DNA vector expressing an HIV epitope and a CTL-epitope fused with HBsAg. The DNA vector construct comprises a CMV promoter operably linked to the HIV env polyepitope

coding region, a MHC class I-restricted epitope (IPQSLDSWWTSL), and a hepatitis antigen epitope (fig. 1), they obtained specific CTL responses to both HIV and HBV in mice as well as rhesus macaques (abstract, tables 2a+2b). *Borgne et al* do not use a hepatitis B core antigen.

Loktev et al supplemented the combined teachings of *Fuller et al, Hanke et al et al* and Borgne et al by establishing that it is well known in the art HB core antigen is the most promising vaccine carrier for exposing foreign antigens to the host immune system compared to other carrier system such as HBsAg, and suitable for use in developing cellular response against HIV antigens. *Loktev et al* teach various approaches to enhance the effectiveness of a molecular vaccine. They teach one of the known approaches is expressing a peptide in a special protein-carrier, such as HBsAg (paragraph bridging pages 129-30). *Loktev et al* go on to teach that the core antigen particles could also be used as a carrier and appears to be the most promising carrier exposing foreign epitopes compared to other means tested (1st & 2nd paragraphs under Discussion section).

Evidently, at the time of instant filing, using multiple dosing regimen and combining DNA vector with a viral vector in the HIV vaccination is well known in the art as taught by *Fuller et al*, enhancing a CTL response to HIV with multi-CTL epitope and a hepatitis core antigen carrier are also well known in the art as taught by *Hanke et al, Borgne et al,* and *Loktev et al*; and it is also known that the CTL response to a polynucleotide encoding a HIV antigen, a multi-CTL epitope, and a hepatitis viral antigen are similar in mice and primates as taught by *Borgne et al.* Accordingly, it

would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Fuller et al,* by simply combining various approaches known in the art with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because the different approaches would result in a synergistic effect in enhancing the CTL response, thus the HIV vaccine efficacy. Although none of the references taught the levels of CTLs elicitated as claimed in claim 1, given the effectiveness taught in each of the individual reference, the skilled artisan would have had a reasonable expectation of success in combining multiple enhancing approaches taught in the cited references, and arriving at an effective vaccine composition that could induce the recited levels of CTLs. Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

In the response filed 5/4/04, Applicants representative reiterated the view of Dr. Watkins expressed during an interview after the final rejection, which pointing to the difference of each reference compared to the instantly claimed invention, and argue that the references either singly or combined do not teach that the response would be at the level that Applicants have found.

The argument has been fully considered but found not persuasive.

As an initial matter, it is noted that the rejection of record is based on the combined teachings of references, while the analysis attacks the reference individually. The court has ruled that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re*

Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With respect to the CTL vs. antibody and Th response taught by Fuller and Loktev references, administering an antigen in a subject could induce many different types of immune responses, Fuller and Loktev references did not measure CTL response, which is not an evidence that the CTLs were not present. The combined teachings of the references further teach the necessity and means to induce the CTL responses, and thus provides suggestion and means to induce the CTL response. It is also noted that Loktev et al reference is relied upon for the knowledge of HB core antigen, not for the effects of CTL response.

With respect to the surprising high levels of the CTL response of instantly claimed process as compared to the levels obtained by *Hanke et al*, it is noted that the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. MPEP 716.01(c). Therefore, the assertion needs to be supported by an appropriate affidavit or declaration.

With respect to the *Borgne et al* reference, applicants indicated that the data presented in the publication are confusing. In response, the reference is relied upon for

the showing of using a hepatitis B virus-based vector to induce a strong CTL response against an HIV antigen epitope, and the similarity of inducing such response in mice and primates. Whether the data presented are surprising or confusing or not does not negate the basis relied upon in the construction of the 103 rejection,.

Accordingly, for reasons set forth above, the rejection stands.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Q. Janice Li
Primary Patent Examiner
Art Unit 1632

QL
August 24, 2004